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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/424,521    02/15/00    NIELSEN    P    ISIS-3070

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EXAMINER

LARSON, T

ART UNIT

PAPER NUMBER

1635

DATE MAILED:

10/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Advisory Action**

Application N .

09/424,521

Applicant(s)

NIELSEN ET AL.

Examiner

Thomas G. Larson, Ph.D.

Art Unit

1635

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 September 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 02 August 2001. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See attachment.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 15-52.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☒ Other: Note attached interview summary, paper no. 16.

Attachment to advisory action, paper no. 17.

1. Applicant's amendment and arguments submitted 9/24/01 have been considered, but are believed to raise new issues and to require further consideration. The newly recited Markush group for moieties conjugated to the peptide nucleic acid PNA (alkyl, lipids and steroids) raises new issues because it is disclosed in document WO 92/20702 (designated "AO" on the PTO-1449 filed 3/17/00) at p. 9, lns. 26 and 27, and in claim 1, paragraph bridging pp. 146-147. Processes for modulating gene expression using the conjugated PNA are also disclosed and are claimed in claims 23-31. Pharmaceutical compositions of the conjugated PNA are also disclosed and claimed in claim 33. Although the preamble for claims 15, 21, 25, and 32 (a method for modulating cellular uptake and distribution of a PNA) does not appear to be explicitly taught in the '702 patent, the preamble appears to be non-limiting because it merely recites the purpose of the process (note MPEP 2111.02). Moreover, the properties of "modulating cellular uptake and distribution of a PNA" appear to be intrinsic to the recited structures. The claiming of a new use or property that is inherent in the prior art does not necessarily make the claim patentable (note MPEP 2112).

2. In light of the prior art discussed above, additional consideration is required to determine if new rejections under 35 USC 102 and/or 103 are appropriate. An

additional search may be warranted if new rejections under 35 USC 103 are required.

3. Because the amendments presented 9/24/01 raise new issues that require additional consideration and potentially require additional search, they are not deemed to place the application into better condition for appeal and the amendment in its present form can not be entered.

4. It is noted that this application may be eligible to claim priority benefit of WO 92/20702. Note that application serial no. 08/054363 claims benefit of WO 92/20702, but this application does not do so. Claiming benefit of WO 92/20702 in this application would obviate the issues set forth in item nos. 1-3 above.

5. Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The OFFICIAL FAX numbers are (703) 308-4242 and (703) 308-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Unofficial papers, such as draft responses and proposed amendments, may be transmitted directly to the examiner's computer at (703) 746-7019. If an official paper is to be faxed to this number, it is recommended that the examiner be notified before doing so.

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Any inquiry concerning this communication or earlier communications should be directed to Thom Larson, whose telephone number is (703) 308-7309. The examiner normally can be reached Monday through Friday from 9:00 AM to 5:30 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Receptionist, whose telephone number is (703) 308-0196.

Thomas G. Larson, Ph.D.  
Examiner



SEAN MCGARRY  
PRIMARY EXAMINER